

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Henry C. Chiou and  
Dennis J. Carlo

Serial No.: Continuation of 09/379,434

Filed: Herewith

For: TARGETED DELIVERY OF GENES  
ENCODING INTERFERON

Attorney Docket No.: TTI-143CPCN2

Group Art Unit: 1632

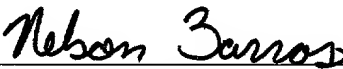
Examiner: Baker, A.

Commissioner for Patents  
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"Express Mail" mailing label number: EL 011 359 655 US

Date of Deposit: November 26, 2001

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Signature

Nelson F. Barros

Please Print Name of Person Signing

**PRELIMINARY AMENDMENT**

Dear Sir:

Prior to examination, please amend the above-referenced patent application as follows:

**In the Specification:**

Please replace the paragraph after the title with the following paragraph:

**-- Related Applications**

This application is a continuation of U.S. Patent Application No. 09/379,434 filed on August 23, 199, which is a continuation of 08/819,238 filed on March 17, 1997, which is a continuation-in-part of U.S. Patent Application No. 08/616,023 filed on March 14, 1996, the contents of which are incorporated by reference herein.--

**In the Claims:**

Please cancel claim 1 without prejudice.

Please add claims 31-46 as follows:

31. (New) An expression vector comprising a liver-specific promoter and a liver-specific enhancer, said promoter and enhancer being derived from different genes.

32. (New) The expression vector of claim 31, wherein the promoter and enhancer are located upstream from the coding sequence of a gene.

33. (New) The expression vector of claim 32, wherein the gene encodes a human interferon protein.

34. (New) The expression vector of claim 33, wherein the human interferon protein is IFN- $\alpha$ .

35. (New) The expression vector of claim 33, wherein the gene encodes a human IFN- $\alpha$ 2b protein.

36. (New) The expression vector of claim 31, wherein the liver-specific promoter is the human thyroid binding globulin promoter.

37. (New) The expression vector of claim 31, wherein the liver-specific enhancer is the alpha-1 microglobulin/bikunin enhancer.

38. (New) The expression vector of claim 32 further comprising one or more introns located (a) downstream from the promoter and enhancer and (b) upstream from the coding sequence.

39. (New) The expression vector of claim 38, wherein the intron is located within the leader sequence of the gene.

40. (New) An expression vector comprising the human thyroid binding globulin promoter and the alpha-1 microglobulin/bikunin enhancer.

41. (New) The expression vector of claim 40 comprising two or more copies of the alpha-1 microglobulin/bikunin enhancer.

42. (New) The expression vector of claim 40, wherein the human thyroid binding globulin promoter and the alpha-1 microglobulin/bikunin enhancer are located upstream from the coding sequence of a gene.

43. (New) The expression vector of claim 42, wherein the coding sequence is also preceded upstream by a leader sequence comprising one or more introns.

44. (New) The expression vector of claim 42, wherein the gene encodes a human interferon protein.

45. (New) The expression vector of claim 44, wherein the human interferon protein is IFN- $\alpha$ .

46. (New) The expression vector of claim 44, wherein the gene encodes a human IFN- $\alpha$ 2b protein.

### REMARKS

Claim 1 has been cancelled herein. Claims 2-30 have been cancelled in the application transmittal letter submitted herewith. New claims 31-51 have been added herein. Accordingly, claims 31-51 are currently pending in the present application. For the Examiner's convenience, a copy of the currently pending claims is attached hereto as an appendix entitled "Version With Markings to Show Changes Made."

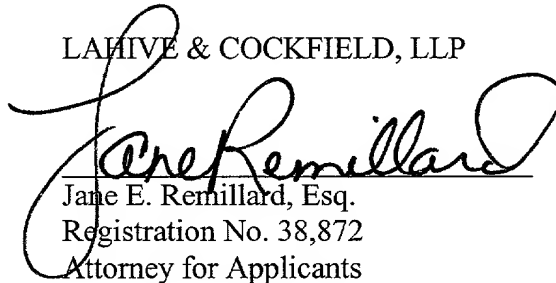
No new matter has been added. Support for the newly added claims can be found in the instant specification as well as the claims as originally filed. Specifically, support for new claims 31-46 can be found, for example, at page 7, lines 15-18, as well as in Figure 7 (and its Figure description on page 4), and in the Exemplification section of the application (see *e.g.*, page 17, lines 1-8).

### CONCLUSION

If the Examiner has any questions or believes that a telephone conversation with the Applicants' attorney would be helpful in expediting allowance of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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Dated: November 26, 2001

**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Specification:**

The paragraph after the title was replaced with the following paragraph:

**-- Related Applications**

This application is a continuation of U.S. Patent Application No. 09/379,434 filed on August 23, 1999, which is a continuation-in-part of U.S. Patent Application No. 08/616,023 filed on March 14, 1996, the contents of which are incorporated by reference herein.--

**In the Claims:**

Claim 1 was cancelled without prejudice.

Claims 31-46 were added as follows:

31. **(New)** An expression vector comprising a liver-specific promoter and a liver-specific enhancer, said promoter and enhancer being derived from different genes.

32. **(New)** The expression vector of claim 31, wherein the promoter and enhancer are located upstream from the coding sequence of a gene.

36. **(New)** The expression vector of claim 32, wherein the gene encodes a human interferon protein.

37. **(New)** The expression vector of claim 33, wherein the human interferon protein is IFN- $\alpha$ .

38. **(New)** The expression vector of claim 33, wherein the gene encodes a human IFN- $\alpha$ 2b protein.

36. (New) The expression vector of claim 31, wherein the liver-specific promoter is the human thyroid binding globulin promoter.

37. (New) The expression vector of claim 31, wherein the liver-specific enhancer is the alpha-1 microglobulin/bikunin enhancer.

38. (New) The expression vector of claim 32 further comprising one or more introns located (a) downstream from the promoter and enhancer and (b) upstream from the coding sequence.

39. (New) The expression vector of claim 38, wherein the intron is located within the leader sequence of the gene.

40. (New) An expression vector comprising the human thyroid binding globulin promoter and the alpha-1 microglobulin/bikunin enhancer.

41. (New) The expression vector of claim 40 comprising two or more copies of the alpha-1 microglobulin/bikunin enhancer.

42. (New) The expression vector of claim 40, wherein the human thyroid binding globulin promoter and the alpha-1 microglobulin/bikunin enhancer are located upstream from the coding sequence of a gene.

43. (New) The expression vector of claim 42, wherein the coding sequence is also preceded upstream by a leader sequence comprising one or more introns.

45. (New) The expression vector of claim 42, wherein the gene encodes a human interferon protein.

45. (New) The expression vector of claim 44, wherein the human interferon protein is IFN- $\alpha$ .

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46. (New) The expression vector of claim 44, wherein the gene encodes a human IFN- $\alpha$ 2b protein.

46. (New) The expression vector of claim 44, wherein the gene encodes a human IFN- $\alpha$ 2b protein.